

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICALS U.S.A.,)	
INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 19-2216-RGA
)	
MYLAN PHARMACEUTICALS INC.,)	
)	
Defendant.)	

**REPLY IN SUPPORT OF
PAR PHARMACEUTICAL INC.'S MOTION TO INTERVENE**

OF COUNSEL:
Elizabeth J. Holland
Jeffrey A. Simes
GOODWIN PROCTER LLP
The New York Times Building
620 Eighth Avenue
New York, NY 10018
(212) 813-8800

Samuel E. C. Sherry
Christie L. Larochelle
GOODWIN PROCTER LLP
100 Northern Avenue
Boston, MA 022210
(617) 570-1000

John W. Shaw (No. 3362)
Karen E. Keller (No. 4489)
David M. Fry (No. 5486)
SHAW KELLER LLP
I.M. Pei Building
1105 North Market Street, 12th Floor
Wilmington, DE 19801
(302) 298-0700
jshaw@shawkeller.com
kkeller@shawkeller.com
dfry@shawkeller.com
*Attorneys for Intervenor-Plaintiff
Par Pharmaceutical, Inc.*

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Federal Rule of Civil Procedure 24(a)	2, 3, 5, 9, 10
Federal Rule of Civil Procedure Rule 24(b)	1, 2, 5, 9, 10

Par Pharmaceutical, Inc. (“Par”) respectfully submits this Reply Brief in further support of its motion to intervene in the above-captioned action between Plaintiff Takeda Pharmaceutical U.S.A., Inc. (“Takeda”) and Defendant Mylan Pharmaceuticals Inc. (“Mylan”) (D.I. 26) and in reply to Takeda’s answering brief (D.I. 62).

INTRODUCTION

Takeda’s opposition proposes that the common factual and legal issues underlying both Takeda’s and Par’s claims be resolved in two separate, overlapping lawsuits. Such a needless proliferation of lawsuits serves no one’s interest, much less judicial economy. Both sets of claims concern the same unlawful acts by Mylan and overlapping injuries to Takeda and Par. Under Takeda’s proposal, the same witnesses would provide the same testimony regarding the same documents to support the same legal conclusions in two separate trials to two separate juries, possibly producing two different results. That is not, and cannot be, what Rule 24 intends.

The transactions at the center of this dispute are Mylan’s sales and proposed sales of its ANDA product, which infringe Takeda’s patents, breach the Takeda-Mylan settlement agreement and interfere with Par’s business relationships. Par thus has a direct interest in both preventing Mylan from relaunching its ANDA product and receiving compensation for Mylan’s unlawful acts. Nor do Par’s claims meaningfully expand the scope of litigation. Takeda already placed the damage to Par’s authorized generic at issue in this litigation by specifically attacking Mylan’s interference with Par’s business relationships as an example of Mylan’s misconduct. Moreover, Takeda seeks damages for lost profits (including profits from Par’s authorized generic) and willful infringement, thereby placing at issue both damages to Par and the deliberate nature of Mylan’s interference with Par’s distribution network.

Although Par need not demonstrate a lack of adequate representation for intervention under Rule 24(b), Par’s interests in this case are nonetheless not adequately represented. First,

although Takeda seeks recovery for *its* share of the lost profit associated with the authorized generic, no existing party seeks redress for *Par's* injuries arising from the same facts. Second, the importance of the authorized generic to Par's generic portfolio renders Par more sensitive to disruptions in the colchicine market, a concern that Takeda ignored in its preliminary injunction briefing. Third, Mylan's principal defense in this matter appears to be that Takeda erred in drafting its settlement with Mylan. Takeda cannot be said to adequately represent Par's interests when it is accused of being responsible for the damage to Par.

Finally, Par has standing to assert its patent claims because the operation of the Takeda-Par agreement makes Par Takeda's sole licensee and therefore a proper co-plaintiff. There is, however, no need for the Court to reach the issue of Par's standing to assert its patent claims as Par indisputably has standing to assert its state law claims. This is sufficient to grant this motion under either Rule 24(a) or Rule 24(b).

ARGUMENT

A. Par's Claims and Takeda's Claims Arise from the Same Transactions and Involve the Same Issues of Fact and Law

The operative core of Par's claims is already at issue in this litigation, and intervention is therefore proper under either Rule 24(a)(2) or Rule 24(b)(1)(B). The transactions and acts that precipitated Takeda's complaint were Mylan's unlawful sales and offers for sale of its ANDA product. Par has a direct interest in these transactions because they interfered with Par's business relationships as Takeda's authorized generic. For this reason, the legal and factual questions regarding breach, infringement, willful interference and the corresponding damage lie at the foundation of both Takeda's and Par's claims.

The Third Circuit requires that "intervenors [] have an interest that is specific to them, is capable of definition, and will be directly affected in a substantially concrete fashion by the relief

sought.” *Kleissler v. U.S. Forest Serv.*, 157 F.3d 964, 972 (3d Cir. 1998). This standard, however, does not require a direct interest in *every* aspect of the dispute. *See, e.g., ACR Energy Partners, LLC v. Polo North Country Club, Inc.*, 309 F.R.D. 191 (D.N.J. 2015) (allowing intervention under Rule 24(a) due to security interest in property notwithstanding absence of direct interest in disputed contract, which concerned provision of energy to said property). Par’s interest in Mylan’s unlawful product sales is specific, defined, and directly affected by the requested injunctive and compensatory relief. In this respect, Par is similar to the intervening retailer in *Michaels Stores, Inc. v. Castle Ridge Plaza Associates*, 6 F.Supp.2d 360 (D.N.J. 1998) who was granted intervention under Rule 24(a) due to an exclusivity interest in its lease that was threatened by a party-competitor seeking to open a location in the same complex. Even assuming for the sake of argument that Takeda were correct that Par lacks an interest in the patents and contracts that render Mylan’s sales unlawful, Mylan’s sales are the *casus belli* of Takeda’s complaint. Par’s interest in those transactions is indisputable.

If that were not enough, Takeda directly raised the issue of Par’s injury in its complaint. As examples of Mylan’s illicit behavior, Takeda cites Mylan’s improper contact with Par’s authorized generic customers (D.I. 25 ¶ 66); a customer that Par lost due to this contact (D.I. 25 ¶ 67); and Mylan’s damage to Takeda by, *inter alia*, reducing “the Takeda/Par authorized generic product’s share of the market.” (D.I. 25 ¶ 71). Takeda cannot reasonably argue that Par has no interest in this action when Takeda’s own complaint puts Par’s injuries at issue.

Par’s most important questions of fact and law are likewise Takeda’s. All of the present claims turn on the unlawfulness of Mylan’s sales. Takeda’s breach of contract claim, Par’s state law claims, Takeda’s (and Par’s) patent infringement claims each concern the same legal and factual questions regarding whether Mylan’s sales are prohibited under the Takeda-Mylan

settlement agreement and whether they infringe the patents-in-suit. Mylan will likely assert a nearly identical defense to both sets of claims.

Nor would Par's claims significantly expand the scope of this litigation. Par's tortious-interference claim requires Par to demonstrate: (1) that there was a contract; (2) that Mylan knew about the contract; (3) an intentional act by Mylan that was a significant factor in causing a breach or termination of the contract; (4) that the act was without justification; and (5) that the act caused injury. *Bhole, Inc. v. Shore Investments, Inc.*, 67 A.3d 444, 453 (Del. 2013). That Mylan's sales were unlawful, and thus without justification (element 4), is at issue already. So are the other four elements. Much of Takeda's lost profits claim is based on the payments it receives in connection with Par's sales of the authorized generic. D.I. 25 ¶ 71, 98; D.I. 53 ¶ 18. The existence of Par's distribution relationships (element 1) and the injury to Par (element 5) are therefore already part of this dispute. Takeda also claims enhanced damages for willful infringement, similarly placing at issue Mylan's intentional and unlawful sales (element 3) to entities that Mylan knew were customers of the authorized generic (element 2). D.I. 25 ¶ 189. Since Par's prospective authorized generic sales also amount to profits for Takeda, the facts and legal questions regarding Par's unfair competition claim are likewise already a part of this case.

B. Separate Lawsuits Would be Highly Inefficient

Takeda's demand for separate but duplicative litigations simply makes no sense. The unlawfulness of Mylan's sales (*i.e.* Takeda's case-in-chief) is a core component of Par's claims. Therefore, almost every document and deposition in the Takeda-Mylan matter would have to be produced or taken in a separate action by Par. Conversely, Par's claims against Mylan are components of Takeda's damages case, and so discovery in Par's hypothetical separate litigation would need to be reproduced here. Separate preliminary injunction motions and separate trials with the same witnesses, the same documents, the same issues and the same arguments would be

wildly inefficient. Moreover, Takeda appears to propose that separate juries should hear the same arguments, possibly generating different outcomes. This whole procedure is wasteful and increases the risk of inconsistency and confusion.¹

The rules for intervention are specifically designed to avoid this scenario. The Third Circuit, quoting *Wright and Miller*, states that the purpose of Rule 24 is to allow intervention by those who – like Par here – may suffer disadvantage by the outcome of a case. *Kleissler*, 157 F.3d at 970 (“The central purpose of the 1966 amendment was to allow intervention by those who might be practically disadvantaged by the disposition of the action”) (quoting 7C Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, *FEDERAL PRACTICE AND PROCEDURE: CIVIL* 2D § 1908, at 301 (1986)); *see also Atlantis Dev. Corp. v. United States*, 379 F.2d 818, 824 (5th Cir. 1967) (“[T]he great public interest, especially in these explosive days of ever-increasing dockets, [is in] having a disposition at a single time of as much of the controversy to as many of the parties as is fairly possible consistent with due process.”). Here, judicial efficiency and due process are both served by allowing resolution of these issues in a single litigation. Notably, Mylan – the Defendant in Par’s complaint – does not oppose intervention, which is a further indication that resolving Takeda’s and Par’s claims in a single proceeding is sensible.

C. Takeda Does Not Represent Par’s Interests

Although the common issues of law and fact and the inefficiency of separate trials warrant allowing intervention under Rule 24(b), intervention should also be granted as a matter of right under Rule 24(a) because Takeda does not adequately represent Par’s interests. First, Takeda is not seeking to recover profits lost *by Par* in connection Mylan’s unauthorized sales,

¹ Of course, the Court could avoid this scenario by consolidating the cases for discovery and trial. However, if that is how parallel proceedings would be conducted, then the same outcome is more directly and efficiently achieved by granting Par’s motion.

and thus does not adequately represent Par's interest in damages. Second, the authorized generic plays a large role in Par's generic portfolio, and thus Mylan's unauthorized product poses a greater risk to Par. Takeda has not adequately defended Par from this risk in briefing. Lastly, Mylan's defense to this action effectively accuses Takeda of being responsible for the damages to Par, making it impossible for Takeda to represent Par's interests here.

As the Supreme Court has held, an intervenor need only show that "representation of his interest *may be* inadequate; and the burden of making that showing should be treated as minimal." *Trbovich v. United Mine Workers*, 404 U.S. 528, 538 n. 10 (1972) (emphasis added; internal quotes omitted). The Third Circuit explains that the applicant's interest should be compared to the interests of the parties already in the litigation, noting that parties disinterested in (or adverse to) an intervenor's objective do not provide adequate representation. *Mountain Top Condo. Ass'n v. Dave Stabbert Master Builder, Inc.*, 72 F.3d 361, 368–69 (3d Cir. 1995) ("If the interest of the absentee is not represented at all, or if all existing parties are adverse to him, then he is not adequately represented.") (citing *Wright & Miller, supra*, § 1909, at 318–19).

Takeda simply does not represent Par's interests under this standard. Par claims damages from Mylan for *Par's* injuries caused by the unlawful sale of Mylan's infringing ANDA product. Takeda does not seek to recover for injuries to Par. Moreover, Takeda seeks damages through contract law, whereas Par claims damages through tort. The underlying facts overlap, but the corresponding legal arguments are not the same. These differences between Takeda's and Par's interests are sufficient to satisfy the "minimal showing" required under the standard.² *Trbovich*, 404 U.S. at 538 n. 10; *see Brody By & Through Sugzdinis v. Spang*, 957 F.2d 1108, 1124 (3d Cir.

² Moreover, since Takeda and Par both seek damages in connection with the authorized generic, they may find themselves adverse to one another as to how those damages are to be divided between them.

1992) (finding that if an applicant's interests are not sufficiently represented if they may diverge from the party's at the remedial stage, as the Court "cannot expect [the party] to be vigorous in defending the applicants' legal interests.").

That Takeda and Par both seek to enjoin Mylan's sales does not render Takeda an adequate representative of Par. Intervenors commonly share objectives with the parties while also qualifying for intervention under Rule 24. In *Trbovich*, the union members seeking intervention and the government shared a mutual interest in democratic union elections, and yet the Supreme Court found that the government's additional goal of representing the public interest constituted a sufficient divergence of interest to render intervention appropriate. 404 U.S. at 538-39; *see also Pennsylvania v. President of the United States of America*, 888 F.3d 52, 61-62 (3d. 2018) (permitting intervention by religious group who had "related but not identical" interests to the federal government, despite both parties seeking to uphold rules exempting religious organizations from a contraceptive mandate) (quoting *Trbovich*, 404 U.S. at 538). It would simply make no sense if Rule 24 were unavailable if some reasonable overlap of goals exists; this would eviscerate the rule and multiply lawsuits.³⁴

³ Takeda's citation to *Hoots* is not apposite. D.I. 69 at 8-9. Takeda suggests that *Hoots* stands for the proposition that because Par and Takeda both seek to enjoin Mylan, Par's interests are necessarily adequately represented by Takeda. Not so. The *Hoots* court found that the proposed intervenor could not meet the minimal burden to show inadequate representation because its desired goal was *perfectly* aligned with one of the defendants. Both sought to simply maximize the same refund to taxpayers. *Hoots v. Cmwlth of Pa.*, 672 F.2d 1133, 1135 (3d Cir. 1982). Here, Takeda and Par each seek damages for themselves (*i.e.* not a "perfect" alignment), and they seek to do so through the different legal doctrines of contract and tort law. Moreover, *Hoots* held that proposed interveners would be permitted intervention if defendants did not adequately represent their interests. *Id.* Here, Takeda has not sought to prevent the harms specifically directed to Par by Mylan's unlawful reentry. *Cf.* D.I. 47 at 14-17 with D.I. 21 14-16.

⁴ The additional cases cited by Takeda are equally inapplicable, at least in part because each involves a government entity. In the Third Circuit, there is "a well-settled presumption that when a representative party is a government body charged with representing the interests of proposed intervenors . . . it will do so adequately unless there is a showing of gross negligence."

Here, the preliminary injunction briefing demonstrates that Takeda does not adequately represent Par's interest. In Par's brief in support of Takeda's preliminary injunction motion, Par details the specific damages to Par that would be caused by Mylan's reentry into the market, including the importance of the authorized generic to Par and how the balance of hardships between Par and Mylan favor granting an injunction. D.I. 47 at 14-17. To the best of Par's knowledge,⁵ Takeda addressed none of these concerns in its arguments to the Court. *Cf.* D.I. 47 at 14-17 *with* D.I. 21 14-16. *See Michaels Stores*, 6 F.Supp.2d at 365 (finding that applicant's interests are not adequately represented by allied party because an unsuccessful outcome would affect the two differently).

Lastly, Mylan's defense renders Takeda an inadequate representative of Par's interests because Mylan essentially accuses Takeda of being responsible for Par's injury. In its opposition to Takeda's motion for preliminary injunction, Mylan argues that Takeda authorized Mylan's launch (D.I. 70 at 11-14) and is therefore responsible for Par's lost income and lost opportunities.

Benjamin v. Dep't of Pub. Welfare of Cmwltth., 267 F.R.D. 456, 464 (M.D. Pa. 2010). (internal quotations omitted). Takeda's other cases all depend on this principle. For example, *Corman* involved an individual voter who moved to intervene in a case brought by state legislators seeking to invalidate a districting map *after* the case was over and judgment had been entered. *Corman v. Sec'y Cmwltth. of Pa.*, 751 F. App'x 157, 159 (3d Cir. 2018); *see also Acra Turf Club, LLC v. Zanzuccki*, 561 F. App'x 219, 221 (3d Cir. 2014) (denying intervention by New Jersey Thoroughbred Horseman's Association as defendants in case brought against Executive Director of New Jersey Racing Commission); *Nat'l Collegiate Athletic Ass'n v. Corbett*, 296 F.R.D. 342, 344 (M.D. Pa. 2013) (denying intervention by state senator in suit brought against other state officers related to disposition of fine paid by Pennsylvania State University). Here, Takeda is not a government agency charged with representing Par's interests, nor are Takeda's interests fully aligned with Par's in terms of potential damages or remedies. Therefore, none of these cases stands for the proposition that Takeda, a private, for-profit corporation, can or will adequately represent Par's interests in this litigation, particularly in light of the "minimal" showing required to establish this element of Rule 24. *Trbovich*, 404 U.S. at 538 n. 10.

⁵ Par has not received Takeda's sealed brief in support of its preliminary injunction motion.

In light of these allegations, Takeda's interests cannot be said to be in full alignment with Par's.⁶

D. Par Has Standing to Intervene

Takeda does not dispute that Par has standing to bring its intentional interference and unfair competition claims. Accordingly, lack of standing is not a basis for denial of Par's intervention motion. Par's state law claims provide a basis for intervention under either Rule 24(a)(2) or Rule 24(b)(1)(B).

In any event, Takeda's argument that Par lacks standing to assert its patent claims fails. Whether a party is an "exclusive licensee" for purposes of joining an action is determined by the actual business relationship between the parties, not particular words or titles used in a license agreement. *See Ortho Pharm. Corp. v. Genetics, Inc.*, 52 F.3d 1026, 1032 (Fed. Cir. 1995) ("[I]t is the licensee's beneficial ownership of a right to prevent others from making, using or selling the patented technology that provides the foundation for co-plaintiff standing, not simply that the word 'exclusive' may or may not appear in the license."). Here, the Takeda-Par agreements ensure Par's exclusivity by subjecting Takeda to severe consequences if it authorizes another generic. For example, a failure by Takeda to enforce exclusivity would authorize Par to launch its own ANDA product royalty-free, effectively subjecting Takeda to the damage that Mylan threatens here and that Takeda sues to avoid. *See* D.I. 25 ¶62 ("settlements authorize the licensed generic-drug manufacturers to begin marketing their own generic versions of

⁶ Takeda asserts, without support, that Par's ability to protect its interests would not be impaired by the denial of Par's motion. This is plainly incorrect. There can be no reasonable doubt that an adverse finding for Takeda in this case would have a material negative effect on Par's intentional interference and unfair competition claims. *See* Fed. R. Civ. P. 24 advisory committee's notes to 1966 Amendment ("If an absentee would be substantially affected in a practical sense by the determination made in an action, he should, as a general rule, be entitled to intervene."); D.I. 47 at 10-11.

Colcrys[®]"); D.I. 29 ¶ 13; D.I. 50 ¶¶ 25-27 (examining lost AG revenues⁷ upon a new entrant into the market). These significant consequences assure both parties that Takeda will maintain Par as an exclusive supplier. Regardless of the fact that the contract uses the words "non-exclusive", its operation makes Par's exclusivity clear.

CONCLUSION

For the foregoing reasons, Par respectfully requests that the Court grant its motion to intervene, either as a matter of right under Rule 24(a)(2) or, in the alternative, permissively under Rule 24(b)(1)(B).

Respectfully submitted,

/s/ Karen E. Keller

John W. Shaw (No. 3362)

Karen E. Keller (No. 4489)

David M. Fry (No. 5486)

SHAW KELLER LLP

I.M. Pei Building

1105 North Market Street, 12th Floor

Wilmington, DE 19801

(302) 298-0700

jshaw@shawkeller.com

kkeller@shawkeller.com

dfry@shawkeller.com

Attorneys for Intervenor-Plaintiff

Par Pharmaceutical, Inc.

OF COUNSEL:

Elizabeth J. Holland

Jeffrey A. Simes

GOODWIN PROCTER LLP

The New York Times Building

620 Eighth Avenue

New York, NY 10018

(212) 813-8800

Samuel E. C. Sherry

Christie L. Larochelle

GOODWIN PROCTER LLP

100 Northern Avenue

Boston, MA 022210

(617) 570-1000

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⁷ Calculations do not account for Takeda's further losses associated with branded Colcrys[®].